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**Patent and Trademark Office**

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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
08/786,937	01/22/97	BOUCHARD	P 235299/96001 <sup>mk</sup>

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HM22/0303

EXAMINER	
DELACROIX MUIRHEI, C	
ART UNIT	PAPER NUMBER
1654	12

DATE MAILED: 03/03/99

**Please find below and/or attached an Office communication concerning this application or proceeding.**

**Commissioner of Patents and Trademarks**

# Office Action Summary

Application No.

081786,937

Applicant(s)

Bouchard et al

Examiner

C. Delacroix

Group Art Unit

1654

—The MAILING DATE of this communication appears on the cover sheet beneath the correspondence address—

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, such period shall, by default, expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).

## Status

- ☒ Responsive to communication(s) filed on 12/22/98
- ☐ This action is **FINAL**.
- ☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

## Disposition of Claims

- ☒ Claim(s) 15, 16, 18-24, 26-33 is/are pending in the application.
- Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- ☒ Claim(s) 15, 16, 18-24, 26-33 is/are rejected.
- ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- ☐ Claim(s) \_\_\_\_\_ are subject to restriction or election requirement.

## Application Papers

- ☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.
- ☐ The proposed drawing correction, filed on \_\_\_\_\_ is ☐ approved ☐ disapproved.
- ☐ The drawing(s) filed on \_\_\_\_\_ is/are objected to by the Examiner.
- ☐ The specification is objected to by the Examiner.
- ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. § 119 (a)-(d)

- ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
- ☐ All ☐ Some\* ☐ None of the CERTIFIED copies of the priority documents have been
- ☐ received.
- ☐ received in Application No. (Series Code/Serial Number) \_\_\_\_\_.
- ☐ received in this national stage application from the International Bureau (PCT Rule 1.7.2(a)).

\*Certified copies not received: \_\_\_\_\_

## Attachment(s)

- ☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). \_\_\_\_\_
- ☐ Interview Summary, PTO-413
- ☐ Notice of Reference(s) Cited, PTO-892
- ☐ Notice of Informal Patent Application, PTO-152
- ☐ Notice of Draftsperson's Patent Drawing Review, PTO-948
- ☐ Other \_\_\_\_\_

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**DETAILED ACTION**

Applicant's request for a continuation under 37 CFR 1.53(d) of prior application 08/786,937, filed 1/22/97 is acknowledged.

***Claim Rejections - 35 USC § 112***

1. Claims 18 and 20 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In claim 18, lines 2 and 3, the phrases "the inhibition of the action of natural LH" and "the follicle development" lack antecedent basis in the claims.

In claim 20, line 3, the term "higher" is a relative term which renders the claim indefinite. The term "higher" is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention.

***Claim Rejections - 35 USC § 102***

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

3. Claims 21, 22 and 33 are rejected under 35 U.S.C. 102(b) as being anticipated by Diedrich et al.

Diedrich et al. disclose a method of inducing ovarian stimulation in tubal sterile patients by administering a combination of exogenous gonadotrophins (HCG) and the LHRH antagonist Cetrorelix to said patients. Cetrorelix was administered at a dosage 3 mg daily starting on day 7 of the menstrual cycle. Please see the abstract; page 789, **Results**, first full paragraph; page 790, second column, first full paragraph; page 791, first column, third paragraph.

Claims 22 and 33 are anticipated by Diedrich because Diedrich discloses administration of the same active agent, i.e. Cetrorelix, to a patient using Applicant's claimed method steps. Accordingly, induction of ovulation between day 9 and 20 of the menstruation cycle is inherent.

***Claim Rejections - 35 USC § 103***

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

5. The factual inquiries set forth in *Graham v. John Deere Co.*, 148 USPQ 459, that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or unobviousness.

6. Claims 15, 16, 18-24, 26-33 are rejected under 35 U.S.C. 103(a) as being unpatentable over Diedrich et al. in view of Felberbaum et al.

Diedrich et al. disclose a method of inducing ovarian stimulation in tubal sterile patients by administering a combination of exogenous gonadotrophins (HCG) and the LHRH antagonist Cetrorelix to said patients. Cetrorelix was administered at a dosage 3 mg daily starting on day 7 of the menstrual cycle. Diedrich also disclose that GnRH agonists given in combination with exogenous gonadotropins also results in more effective stimulation. Please see the abstract; page 789, **Results**, first full paragraph; page 790, second column, first full paragraph; page 791, first column, third paragraph.

Diedrich does not specifically teach treating infertility, yet the Examiner refers to Felberbaum et al. which teaches treating women with tubal infertility with a combination of exogenous gonadotropins (HMG) and Cetorelix, wherein the Cetorelix is administered subcutaneously at 3mg or 1 mg daily starting on day 7 of the menstrual cycle. Kindly refer to the abstract.

It would have been obvious to one of ordinary skill in the art to use the method taught by Diedrich to treat infertility because Felberbaum raises expectation of success by disclosing that ovarian stimulation is induced and further because Felberbaum, in addition to Diedrich, teaches that the disclosed treatment would be effective in the treatment Polycystic Ovary Disease. Furthermore, both Diedrich and Felberbaum disclose administration of the same gonadotropin/Cetorelix combination to a patient using the same method steps and dosages set forth in Applicant's claims. Accordingly, treatment of fertility disorders would have been obvious.

With respect to using LH, LHRH or a LHRH agonist to inducing ovulation instead of HCG (taught by art), such a modification would have been obvious to one of ordinary skill in the art because it is known that the overall effect of LH and its agonists are to induce ovulation.

Concerning claim 5, which recites administration of Cetorelix in an amount in the range of 0.1 to 0.5 mg, optimization of dosage amounts is well within the capability of the skilled artisan.

Finally, with respect to the fact that the claimed method allows for suppression of LH without affecting FSH secretion, the Examiner maintains that Diedrich does disclose suppression of LH surges while also suggesting that under Cetorelix treatment, suppression of FSH is less pronounced. Please see page 790, second full paragraph.

### **Conclusion**

Claims 15, 16, 18-24, 26-33 are rejected.

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Applicant: BOUCHARD et al.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Cybille Delacroix-Muirheid whose telephone number is (703) 306-3227. The examiner can normally be reached on Tue-Fri from 8:30 to 6:00. The examiner can also be reached on alternate Mondays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Cecilia Tsang, can be reached on (703) 308-0254. The fax phone number for this Group is (703) 308-4242.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

CDM



Feb. 28, 1999



Cecilia J. Tsang  
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